



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-0270]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0799. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional

Foodservice and Retail Food Stores Facility Types

OMB Control Number 0910-0799--Extension

I. Background

From 1998 to 2008, FDA's National Retail Food Team conducted a study to measure trends in the occurrence of foodborne illness risk factors, preparation practices, and employee behaviors most commonly reported to the Centers for Disease Control and Prevention as contributing factors to foodborne illness outbreaks at the retail level. Specifically, data were collected by FDA Specialists in retail and foodservice establishments at 5-year intervals (1998, 2003, and 2008) to observe and document trends in the occurrence of the following foodborne illness risk factors:

- Food from Unsafe Sources,
- Poor Personal Hygiene,
- Inadequate Cooking,
- Improper Holding/Time and Temperature, and
- Contaminated Equipment/Cross-Contamination.

FDA developed reports summarizing the findings for each of the three data collection periods, which were released in 2000, 2004, and 2009 (Refs. 1 to 3). Data from all three data collection periods were analyzed to detect trends in improvement or regression over time and to determine whether progress had been made toward the goal of reducing the occurrence of foodborne illness risk factors in selected retail and foodservice facility types (Ref. 4).

Using this 10-year survey as a foundation, in 2013 to 2014, FDA initiated a new study period. This study will span 10 years. FDA completed the baseline data collection in select healthcare, schools, and retail food store facility types in 2015 to 2016, and these data are being evaluated for trends and significance. A second data collection began in 2019 to 2020 and will be completed if it is safe to do so (pending COVID-19 pandemic), and an additional data

collection is planned for 2023 to 2024 (the subject of this information collection request extension). Three data collections are necessary to trend the data.

Table 1.--Description of the Facility Types Included in the Survey

Facility Type	Description
Healthcare Facilities	<p>Hospitals and long-term care facilities foodservice operations that prepare meals for highly susceptible populations as defined as follows:</p> <ul style="list-style-type: none"> Hospitals--A foodservice operation that provides for the nutritional needs of inpatients by preparing meals and transporting them to the patient's room and/or serving meals in a cafeteria setting (meals in the cafeteria may also be served to hospital staff and visitors). Long-term care facilities--A foodservice operation that prepares meals for the residents in a group care living setting such as nursing homes and assisted living facilities. <p>Note: For the purposes of this study, healthcare facilities that do not prepare or serve food to a highly susceptible population, such as mental healthcare facilities, are not included in this facility type category.</p>
Schools (K-12)	<p>Foodservice operations that have the primary function of preparing and serving meals for students in one or more grade levels from kindergarten through grade 12. A school foodservice may be part of a public or private institution.</p>
Retail Food Stores	<p>Supermarkets and grocery stores that have a deli department/operation as described as follows:</p> <ul style="list-style-type: none"> Deli department/operation--Areas in a retail food store where foods, such as luncheon meats and cheeses, are sliced for the customers and where sandwiches and salads are prepared onsite or received from a commissary in bulk containers, portioned, and displayed. Parts of deli operations may include: <ul style="list-style-type: none"> Salad bars, pizza stations, and other food bars managed by the deli department manager. Areas where other foods are cooked or prepared and offered for sale as ready-to-eat and are managed by the deli department manager. <p>Data will also be collected in the following areas of a supermarket or grocery store, if present:</p> <ul style="list-style-type: none"> Seafood department/operation--Areas in a retail food store where seafood is cut, prepared, stored, or displayed for sale to the consumer. In retail food stores where the seafood department is combined with another department (e.g., meat), the data collector will only assess the procedures and practices associated with the processing of seafood. Produce department/operation--Areas in a retail food store where produce is cut, prepared, stored, or displayed for sale to the consumer. A produce operation may include salad bars or juice stations that are managed by the produce manager.

The results of this 10-year study period will be used to:

- develop retail food safety initiatives, policies, and targeted intervention strategies focused on controlling foodborne illness risk factors;
- provide technical assistance to State, local, tribal, and territorial regulatory professionals;
- identify FDA retail work plan priorities; and
- inform FDA resource allocation to enhance retail food safety nationwide.

The statutory basis for FDA conducting this study is derived from the Public Health Service Act (PHS Act) (42 U.S.C. 243, section 311(a)). Responsibility for carrying out the provisions of the PHS Act relative to food protection was transferred to the Commissioner of Food and Drugs in 1968 (21 CFR 5.10(a)(2) and (4)). Additionally, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Economy Act (31 U.S.C. 1535) require FDA to provide assistance to other Federal, State, and local government bodies.

The objectives of this study are to:

- identify the least and most often occurring foodborne illness risk factors and food safety behaviors/practices in select retail food establishments within the United States.
- determine the extent to which food safety management systems and the presence of a certified food protection manager impact the occurrence of foodborne illness risk factors and food safety behaviors/practices; and
- determine whether the occurrence of foodborne illness risk factors and food safety behaviors/practices in delis differs based on an establishment's risk categorization and status as a single-unit or multiple-unit operation (e.g., establishments that are part of an operation with two or more units).

The methodology to be used for this information collection is described as follows. To obtain a sufficient number of observations to conduct statistically significant analysis, FDA will conduct approximately 400 data collections in each facility type. This sample size has been calculated to provide for sufficient observations to be 95 percent confident that the compliance percentage is within 5 percent of the true compliance percentage.

A geographical information system database containing a listing of businesses throughout the United States provides the establishment inventory for the data collections. FDA samples establishments from the inventory based on the descriptions in table 1. FDA does not intend to sample operations that handle only prepackaged food items or conduct low-risk food preparation activities. The "FDA Food Code" contains a grouping of establishments by risk, based on the

type of food preparation that is normally conducted within the operation (Ref. 5). The intent is to sample establishments that fall under risk categories 2 through 4.

FDA has approximately 23 Regional Retail Food Specialists (Specialists) who serve as the data collectors for the 10-year study. The Specialists are geographically dispersed throughout the United States and possess technical expertise in retail food safety and a solid understanding of the operations within each of the facility types to be surveyed. The Specialists are also standardized by FDA's Center for Food Safety and Applied Nutrition personnel in the application and interpretation of the FDA Food Code (Ref. 5).

Sampling zones have been established that are equal to the 175-mile radius around a Specialist's home location. The sample is selected randomly from among all eligible establishments located within these sampling zones. The Specialists are generally located in major metropolitan areas (i.e., population centers) across the contiguous United States. Population centers usually contain a large concentration of the establishments FDA intends to sample. Sampling from the 175-mile radius sampling zones around the Specialists' home locations provides three advantages to the study:

1. It provides a cross-section of urban and rural areas from which to sample the eligible establishments.
2. It represents a mix of small, medium, and large regulatory entities having jurisdiction over the eligible establishments.
3. It reduces overnight travel and therefore reduces travel costs incurred by the Agency to collect data.

The sample for each data collection period is evenly distributed among Specialists. Given that participation in the study by industry is voluntary and the status of any given randomly selected establishment is subject to change, substitute establishments have been selected for each Specialist for cases where the institutional foodservice, school, or retail food

store facility is misclassified, closed, or otherwise unavailable, unable, or unwilling to participate.

Prior to conducting the data collection, Specialists contact the State or local jurisdiction that has regulatory responsibility for conducting retail food inspections for the selected establishment. The Specialist verifies with the jurisdiction that the facility has been properly classified for the purposes of the study and is still in operation. The Specialist ascertains whether the selected facility is under legal notice from the State or local regulatory authority. If the selected facility is under legal notice, the Specialist will not conduct a data collection, and a substitute establishment will be used. An invitation is extended to the State or local regulatory authority to accompany the Specialist on the data collection visit.

A standard form is used by the Specialists during each data collection. The form is divided into three sections: Section 1--“Establishment Information”; Section 2--“Regulatory Authority Information”; and Section 3--“Foodborne Illness Risk Factor and Food Safety Management System Assessment.” The information in Section 1--“Establishment Information” of the form is obtained during an interview with the establishment owner or person in charge by the Specialist and includes a standard set of questions.

The information in Section 2--“Regulatory Authority Information” is obtained during an interview with the program director of the State or local jurisdiction that has regulatory responsibility for conducting inspections for the selected establishment. Section 3--“Foodborne Illness Risk Factor and Food Safety Management System Assessment” includes three parts: Part A for tabulating the Specialists’ observations of the food employees’ behaviors and practices in limiting contamination, proliferation, and survival of food safety hazards; Part B for assessing the food safety management system being implemented by the facility; and Part C for assessing the frequency and extent of food employee hand washing. The information in Part A is collected from the Specialists’ direct observations of food employee behaviors and practices. Infrequent, nonstandard questions may be asked by the Specialists if clarification is needed on the food

safety procedure or practice being observed. The information in Part B is collected by making direct observations and asking followup questions of facility management to obtain information on the extent to which the food establishment has developed and implemented food safety management systems. The information in Part C is collected by making direct observations of food employee hand washing. No questions are asked in the completion of Section 3, Part C of the form.

FDA collects the following information associated with the establishment's identity: establishment name, street address, city, State, ZIP Code, county, industry segment, and facility type. The establishment identifying information is collected to ensure the data collections are not duplicative. Other information related to the nature of the operation, such as seating capacity and number of employees per shift, is also collected. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study.

FDA has collaborated with the Food Protection and Defense Institute to develop a web-based platform in FoodSHIELD to collect, store, and analyze data for the Retail Risk Factor Study. This platform is accessible to State, local, territorial, and tribal regulatory jurisdictions to collect data relevant to their own risk factor studies. For the 2015 to 2016 data collection, FDA piloted the use of hand-held technology for capturing the data onsite during the data collection visits. The tablets that were made available for the data collections were part of a broader FDA initiative focused on internal uses of hand-held technology. The tablets provided for the data collection presented several technical and logistical challenges and increased the time burden associated with the data collection as compared to the manual entry of data collections. For these reasons, FDA will not be incorporating use of hand-held technology in subsequent data collections during the 10-year study period.

When a data collector is assigned a specific establishment, he or she conducts the data collection and enters the information into the web-based data platform. The interface will

support the manual entering of data, as well as the ability to directly enter information in the database via a web browser.

The burden for the 2023 to 2024 data collection is as follows. For each data collection, the respondents will include: (1) the person in charge of the selected facility (whether it be a healthcare facility, school, or supermarket/grocery store); and (2) the program director (or designated individual) of the respective regulatory authority. To provide the sufficient number of observations needed to conduct a statistically significant analysis of the data, FDA has determined that 400 data collections will be required in each of the three facility types. Therefore, the total number of responses will be 2,400 (400 data collections x 3 facility types x 2 respondents per data collection).

The burden associated with the completion of Sections 1 and 3 of the form is specific to the persons in charge of the selected facilities. The burden includes the time it will take the person in charge to accompany the data collector during the site visit and answer the data collector's questions. The burden related to the completion of Section 2 of the form is specific to the program directors (or designated individuals) of the respective regulatory authorities. This burden includes the time it will take to answer the data collectors' questions and is the same regardless of the facility type.

In the *Federal Register* of February 18, 2021 (86 FR 10087), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment.

(Comment) An interested citizen submitted the following comment:

- a. The previous 10-year study conducted by FDA did not mention negative trends in the "other" category, which included information about contamination risk factors as they relate to food or color additives, poisonous or toxic materials, or storage of poisonous or toxic materials for retail sale. This negative trend should be reported.

- b. In the 2013 to 2014 report on restaurants the “other” contamination risk factor did not appear in the report. This should remain the same as the previous 10-year study for comparison purposes.
- c. FDA should keep chemicals as a risk factor for future research on the occurrence of foodborne illness risk factors

(Response) FDA acknowledges the submission of the question from a concerned citizen and provides the following response:

- a. FDA acknowledges the commenter’s concern on a perceived lack of reporting on negative trends within the previous 10-year study.
- b. FDA report on the results of the 2013 to 2014 data collection was the first report with the new study design of the 10-year study. One of the significant design changes from the 1998 to 2008 Study is the reduction of the number of data items from 42 to 10. The focus on the 10 primary data items provides the opportunity to obtain enough observations of food safety practices and procedures to report statistically significant study conclusions and correlations.

In an effort to focus messaging on the most prevalent food safety practices and behaviors found out of compliance, secondary data items (items 11-19) were not reported at that time. FDA focused the report on the primary 10 data items that directly correspond with the foodborne illness risk factors included in the study. The new study design includes “Other Areas of Interest” that support the primary data items or track an area that is not likely to have a sufficient enough number of observations for statistical purposes but is an important food safety practice within the retail segment of the industry--such as Item 18, “Toxic materials are identified, used, and stored properly as outlined in the marking instructions”, (Attachment B). The current data collection continues to collect information on the provisions within the food code that address the safe storage, handling, and use of toxic and poisonous substances. If significant findings occur, FDA

is committed to reporting those findings. From the 2015 data collection forward, FDA will be publishing a topline summary report to include information on data items 11-18. These reports can be accessed at <https://www.fda.gov/retailfoodriskfactorstudy>.

- c. While not listed as one of the five main foodborne illness risk factors in the current study design, controlling chemicals and toxic substances in food service facilities is important to prevent injury and illness and FDA recognizes this. The information gathered in Data Item 18 as described above helps FDA keep a pulse on risky behaviors surrounding toxic or poisonous materials in retail facilities. The purpose of the current 10-year study is primarily to collect information on the five foodborne illness risk factors and study to elucidate relationships between the foodborne illness risk factors and food safety management systems, and certified food protection managers.

To calculate the estimate of the hours per response, FDA uses the average data collection duration for similar facility types during the FDA's 2008 Risk Factor Study (Ref. 3) plus an additional 30 minutes (0.5 hours) for the information related to Section 3, Part B of the form. FDA estimates that it will take the persons in charge of healthcare facility types, schools, and retail food stores 150 minutes (2.5 hours), 120 minutes (2 hours), and 180 minutes (3 hours), respectively, to accompany the data collectors while they complete Sections 1 and 3 of the form. FDA estimates that it will take the program director (or designated individual) of the respective regulatory authority 30 minutes (0.5 hours) to answer the questions related to Section 2 of the form. This burden estimate is unchanged from the last data collection. Hence, the total burden estimate for a data collection in healthcare facility types is 180 minutes (150 + 30) (3 hours), in schools is 150 minutes (120 + 30) (2.5 hours), and retail food stores is 210 minutes (180 + 30) (3.5 hours).

Based on the number of entry refusals from the 2015 to 2016 baseline data collection, we estimate a refusal rate of 2 percent for the data collections within healthcare, school, and retail

food store facility types. The estimate of the time per non-respondent is 5 minutes (0.08 hours) for the person in charge to listen to the purpose of the visit and provide a verbal refusal of entry.

FDA estimates the burden of this collection of information as follows:

Table 2.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	No. of Non-Respondents	No. of Responses per Non-Respondent	Total Annual Non-Responses	Average Burden per Response	Total Hours
2023-2024 Data Collection (Healthcare Facilities)--Completion of Sections 1 and 3	400	1	400	-	-	-	2.5	1,000
2023-2024 Data Collection (Schools)--Completion of Sections 1 and 3	400	1	400	-	-	-	2	800
2023-2024 Data Collection (Retail Food Stores)--Completion of Sections 1 and 3	400	1	400	-	-	-	3	1,200
2023-2024 Data Collection-Completion of Section 2--All Facility Types	1,200	1	1,200	-	-	-	0.5 (30 minutes)	600
2023-2024 Data Collection-Entry Refusals--All Facility Types	-	-	-	24	1	24	0.08 (5 minutes)	1.92
Total								3,601.92

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

II. References

The following references are on display in the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-

7500 and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. “Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000).” Available at: <https://wayback.archive-it.org/7993/20170406023019/https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf>.

2. “FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).” Available at: <https://wayback.archive-it.org/7993/20170406023011/https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf>.

3. “FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009).” Available at: <https://wayback.archive-it.org/7993/20170406023004/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm224321.htm>.

4. FDA National Retail Food Team. “FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998-2008).” (2010). Available at: <https://wayback.archive-it.org/7993/20170406022950/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm223293.htm>.

5. “FDA Food Code.” Available at: <https://www.fda.gov/food/retail-food-protection/fda-food-code>.

Dated: July 28, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-16700 Filed: 8/4/2021 8:45 am; Publication Date: 8/5/2021]